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| 09/874,302 | 06/05/2001 | Robert F. Rioux | MIY-P01-011 | 7588 |

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ROPES & GRAY LLP
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| EXAMINER |
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ALI, SHUMAYA B

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| ART UNIT | PAPER NUMBER |
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 09/874,302 | Applicant(s) RIOUX, ROBERT F. | |
| | Examiner SHUMAYA B. ALI | Art Unit 3771 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/23/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. In response to the office action mailed on 7/25/07, Applicant amended claims 1, 4, 7, 8, 13, and 16. Claims 5 and 10 are previously cancelled. Currently, claims 1, 2, 4, 6-9, and 11-19 are pending in the instant application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-2, 4, 6, 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Benderev et al. US 5,439,467.**

As to claims 1-2, 4 and 6, Benderev discloses a surgical instrument (fig. 1 and 1a) for treating female urinary incontinence, the instrument comprising: a) a handle 110 (fig. 1); b) a shaft 125 extending in a distal direction from the handle and comprising a curved portion (fig. 1a, col. 5, lines 6-9), the shaft being adapted to access interior tissue within a human body; c) a blunt tip 140 (col. 5, lines 12-17) disposed at a distal end of the shaft 125 (fig. 2). If an operator applies strong force to the blunt tip 140, then the tip would be able to provide a blunt dissection; and d) a window 130 (fig. 4) including an L-shaped slot located within a distal end portion of the shaft, the L-shaped slot including a first leg 132C (fig. 4) extending radially inward and a second leg 131A (fig. 4) extending axially in a distal direction from an inner end of the first leg; wherein the shaft is adapted to transvaginally access interior tissue within a female human body (col. 7,

lines 1-4); wherein the window is capable of receiving and retaining a suture or sling; wherein the handle 110 comprises a friction based gripping surface (col. 4, lines 57-59).

As to claims 11-16 and 19, Benderev discloses an element 115 for covering the window 130 (fig. 4); an actuator 122 (fig. 1) for operating the element, the element being movable between an open position, an intermediate position, and a closed position (fig. 4, col. 6, lines 28-37); wherein the window is adapted to receive a suture 165 (fig. 2) or sling when the element is in placed in the open position, the window is adapted to retain a suture or sing when the element is placed in the intermediate position, and the window is adapted to release a suture or sling when the element is placed in the closed position; wherein the actuator comprises a knob 156 (fig. 1, col. 5, lines 49-52) located on the handle; wherein the element comprises a cutting edge 120 (fig. 2); wherein the first leg 132C and the second leg 132A form an angle of about 90 degrees (fig. 4).

With respect to the functional languages in claims 17-18, Benderev's device is fully capable of performing the claimed functions.

Response to Arguments

4. Applicant's arguments filed 11/23/07 have been fully considered but they are not persuasive. With respect to "Applicant disagree and assert that a fair comparison of the blunt tip recites in claim 1 ...distal most apical poriton of the Benderev device" (see page 6 lines 17-23), it should be noted that the "distal most apical portion" is not supported by the claim. Also notice, claim language requires a shaft extending in a distal direction from the handle, and Benderev's probe guide 125 is a shaft extending form a handle 110. According to standard dictionary definition a shaft is a long, slender part, or object. Probe guide 125 is a long, slender part of the

Art Unit: 3771

handle 110. Therefore, Benderev reference reads on claimed invention. On page 6 lines 23 and 24 Applicant further argues that Benderev does not disclose a "blunt tip", however, this argument is not well taken since Benderev in column 5 lines 12-17 discloses engaging face 140 has a tapered distal face which allows the distal end of the shaft 125 to have a blunt surface/tip. On page 6 lines 26-27 and page 7 line 1 Applicant argues that Benderev's probe is "hollow/open" at its distal end because nothing would be filling the space vacated by the probe 115...the probe guide 125 would not have a blunt tip", this argument is not well taken because there is no dictionary definition that supports a blunt tip can not be hollow. Since engaging face 140 is the of the shaft 125, which also curves to give it a blunt surface, Benderev's engaging face reads on claimed blunt tip. On page 7 lines 9 Applicant further argues that surface 140 will not allow "blunt dissection of tissue", however, this argument is not well taken because if an operator applies strong force on surface 140 then surface 140 will penetrate into tissue, thereby would provide blunt dissection. Therefore, rejection to claims 1-2, 4, 6, and 11-19 using Benderev reference is maintained.

Allowable Subject Matter

5. Claims 7-9 are allowable over the prior art of record.
6. The following is an examiner's statement of reasons for allowance: as to claim 7, the prior art of record does not teach nor render obvious the overall claimed combination of a device for deploying an implant comprising a body including a pair of proximal tabs located adjacent to and spaced apart from the shield, the pair of proximal tabs being adapted to bend inward to drive the shield outward. Therefore, the invention defined in claim 7 is considered novel.

Art Unit: 3771

7. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hoppe (3,372,477) pertains to blunt tip surgical instrument.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHUMAYA B. ALI whose telephone number is (571)272-6088. The examiner can normally be reached on M-W-F 9 am - 5 pm.

Art Unit: 3771

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shumaya B. Ali /
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771